1001 Pennsylvania Avenue, NW, Washington, DC 20004-2595 ▪ p202 624-2500 ▪ f202 628-5116

crowell moring

September 21, 2001

BOX PCT
Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Attorney Docket No 2234/50345

Re: Transmittal Letter to the United States
Designated/Elected Office (DO/EO/US)
Concerning a Filing Under 35 U.S.C. §371

International Application No.: PCT/DE00/00817
International Filing Date: 22 March 2000

Priority date claimed: 22 March 1999
Priority application number: 199 12 933.9

Inventorship: Jürgen STRUBE
Peter STOLZ
Walter MAIER
Wolfgang GUTBERLET

Title: METHOD FOR PRODUCING A POTENTIATED PHARMACEUTICAL PRODUCT

Enclosed herewith for entering the national stage in the United States is the above-referenced international application.

APPLICANT WISHES THAT THE ANNEXES TO THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT REPLACE THE APPROPRIATE PAGES OF THE CLAIMS AS FILED.

1. [X] This is a FIRST submission of items concerning a filing under 35 U.S.C. §371.

2. [ ] This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. §371.

3. [ ] This express request to begin national examination procedures (35 U.S.C. §371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. §371(b) and PCT Articles 22 and 39(1).

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4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. [ ] A copy of the International Application as filed (35 U.S.C. §371(c)(2))

   a. _____ is transmitted herewith (required only if not transmitted by the International Bureau).

   b. __X__ has been transmitted by the International Bureau

   c. _____ is not required, as the application was filed in the United States Receiving Office (RO/US)

6. [X] A translation of the International Application into English (35 U.S.C. §371(c)(2)).

7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. §371(c)(3))

   a. _____ are transmitted herewith (required only if not transmitted by the International Bureau)

   b. __X__ have been transmitted by the International Bureau

   c. _____ have not been made; however, the time limit for making such amendments has NOT expired

   d. _____ have not been made and will not be made

8. [X] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. §371(c)(3)).

9. [X] An oath or declaration of the inventor(s) (35 U.S.C. §371(c)(4)) is:

   [ ] Attached in the regular manner.
   [X] NOT included, but deferred under P.L. 97-247.

INTERNATIONAL APPLN. NO.: PCT/DE00/00817
ATTORNEY DOCKET NO.: 48602

10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5))

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. [ ] An Assignment of the invention in favor of the following organization is enclosed for recordation. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. [X] A FIRST Preliminary Amendment.

[ ] A SECOND or SUBSEQUENT Preliminary Amendment.

14. [ ] A substitute specification.

15. [ ] A change of power of attorney and/or address letter.

16. [X] Other items of information:

[ ] Form PCT/RO/101 Request (in English/in French)

[ ] Small Entity Declaration Under 37 C.F.R. 1.27

[ ] Copy of Form PCT/DO/EI/905 (Notification of Missing Requirements)

[ ] _____ Sheets of Formal Drawings
[ ] _____ Sheets of Informal Drawings

[ ] The content of the paper and computer readable copy of the attached Sequence Listing, submitted in accordance with 37 CFR §1.821(c) and (e), respectively, are the same.

[X] Kindly appoint as associate attorneys (if not already a principal attorney) or agents:

Herbert I. Cantor, Reg. No. 24,392; James F. McKeown, Reg. No. 25,406; Donald D. Evenson, Reg. No. 26,160; Joseph D. Evans, Reg. No. 26,269; Gary R. Edwards, Reg. No. 31,824; and Jeffrey D. Sanok, Reg. No. 32,169

INTERNATIONAL APPLN. NO.: PCT/DE00/00817
ATTORNEY DOCKET NO.: 2234/50345

[X] The total amount due for the filing fee in this case is:

[X] Based on Small Entity Status

Total Number of Claims: 18
Total Independent Claims: 1

Basic filing fee, $860/$430.	$ 430.00
Independent Claims above 3, $80/$40 ea.. . . .	$
Total claims in excess of 20, $18/$9 ea. . . .	$
Multiple dependency penalty, $270/$135	$ 135.00
Declaration surcharge, $130/65	$ 65.00
English translation surcharge, $130	$
TOTAL FILING FEE DUE	$ 630.00

Please forward all communications regarding this application to the undersigned at the letterhead address.

Respectfully submitted,

Herbert I. Cantor
Reg. No. 24,392

HIC/tcv

THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY FEES WHICH MAY BE REQUIRED OR CREDIT ANY OVERPAYMENT TO DEPOSIT ACCOUNT NO. 05-1323. THIS FORM IS FILED IN DUPLICATE.

THIS IS A GENERAL AUTHORIZATION EXCLUDING ONLY PAYMENT OF THE ISSUE FEE.

Attorney Docket: 2234/50345
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	JUERGEN STRUBE ET AL	
Serial No.:	TO BE ASSIGNED	Group Art Unit:
Filed:	CONCURRENT HEREWITH	Examiner:
Title:	METHOD FOR PRODUCING A POTENTIATED PHARMACEUTICAL PRODUCT	

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to calculation of the filing fee and prior to examination, please amend the above-identified application as follows:

IN THE SPECIFICATION

Page 9, line 1, cancel the heading "Claims" and insert the heading -- WHAT IS CLAIMED IS:--

IN THE CLAIMS

Please amend Claim 1 as follows:

--1. (Amended) A method for producing a potentiated pharmaceutical product comprising contacting said pharmaceutical product with a potentiating agent, said potentiating agent containing at least one of bound amino acids and free amino acids, the content of said bound amino acids, when present, being more than 400 nmoles/L, and the content of said free amino acids, when present, being more than 200 nmoles/L.--

Please cancel Claim 3 without prejudice or disclaimer.

Please amend Claims 4 and 6-11 as follows:

--4. (Amended) The method of claims 1 or 2, wherein the bound and/or free amino acids are added to the potentiating medium as accompanying materials.

6. (Amended) The method of claim 1 or 2, wherein the bound and/or amino acids are produced by adding natural, distilled fruit alcohol.

7. (Amended) The method of claim 1 or 2, wherein a fruit alcohol with a high content of amino acids is used as the potentiating agent.

8. (Amended) The method of claim 7, wherein an alcohol from blackthorn is used as the potentiating agent .

9. (Amended) The method of claim 1 or 2, wherein the free and/or bound amino acids are added by contact of the potentiating agent with natural air.

10. (Amended) The method of claim 1 or 2, wherein water is used as the potentiating agent.

11. (Amended) The method of claim 1 or 2, wherein lactose is used as the potentiating agent.--

IN THE ABSTRACT

Please insert the Abstract submitted herewith on a separate page.

REMARKS

It is respectfully request that the above amendments be entered prior to calculation of the filing fee and prior to examination. These amendments have been made to place the application in better form for U.S. practice. No new matter has been inserted.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket #2234/50345).

Respectfully submitted,

September 21, 2001

Herbert I. Cantor
Registration No. 24,392

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P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
HIC:tcv

APPENDIX

Please amend Claim 1 as follows:

--1. (Amended) A method for producing a potentiated pharmaceutical product [for use in man, animals or plants, wherein] comprising contacting said pharmaceutical product with a potentiating agent [is used, the content of] , said potentiating agent containing at least one of bound amino acids [of which is more than 400 nmoles/L and/or of] and free amino acids, the content of [which is] said bound amino acids, when present, being more than 400 nmoles/L, and the content of said free amino acids, when present, being more than 200 nmoles/L[, which are higher than that of the presently used potentiating media].--

Please amend Claims 4 and 6-11 as follows:

--4. (Amended) The method of [at least one of the preceding] claims 1 or 2, wherein the bound and/or free amino acids are added to the potentiating medium as accompanying materials.

6. (Amended) The method of [at least one of the preceding claims] claim 1 or 2, wherein the bound and/or amino acids are produced by adding natural, distilled fruit alcohol.

7. (Amended) The method of [at least one of the preceding claims] claim 1 or 2, wherein a fruit alcohol with a high content of amino acids is used as the potentiating agent.

8. (Amended) The method of claim 7, wherein an alcohol from blackthorn is used as [a fruit alcohol] the potentiating agent .

9. (Amended) The method of [at least one of the preceding claims] claim 1 or 2, wherein the free and/or bound amino acids are added by contact of the potentiating agent with natural air.

10. (Amended) The method of [at least one of the preceding claims] claim 1 or 2 , wherein water is used as the potentiating agent.

11. (Amended) The method of [at least one of the preceding claims] claim 1 or 2 , wherein lactose is used as the potentiating agent.--

SMALL ENTITY DECLARATION

☒ APPLICANT OR PATENTEE KWALIS Qualitätsforschung Fulda GmbH

☒ SERIAL NO. 09/937,151 ☐ PATENT NO _____ ATTORNEY'S DOCKET NO 2234/50345

☒ FILED ~~OR ISSUED~~ September 21, 2001 ☐ SUBMITTED HEREWITH

FOR METHOD FOR PRODUCING A POTENTIATED PHARMACEUTICAL PRODUCT

I(we) hereby declare that I(we) am(are) entitled to the benefit of small entity status with respect to the above-identified application or patent for purposes of paying reduced fees under 35 USC 41(a) & (b) to the U.S. Patent and Trademark Office.

☐ A. INDEPENDENT INVENTOR
I(we) qualify as a(n) independent inventor(s) as defined in 37 CFR 1.9(c).

☐ B. INDIVIDUAL NON-INVENTOR
I would qualify as an independent inventor as defined in 37 CFR 1.9(c) if I had made the invention.

☒ C. SMALL BUSINESS CONCERN
I am ☐ THE OWNER ☒ AN OFFICIAL of the small business concern identified below and am empowered to act on behalf of the concern. The concern qualifies under 37 CFR 1.9(d) and 13 CFR 121.3-18. Rights under contract or law have been conveyed to and remain with the concern and are exclusive unless a checkmark is placed here ☐ and another Declaration on behalf of another entity is filed herewith.

☐ NON-PROFIT ORGANIZATION
I am an official empowered to act on behalf of the non-profit organization identified below. The organization qualifies under 37 CFR 1.9(e), sub-section: ☐ (1) ☐ (2) ☐ (3) ☐ (4). Rights under contract or law have been conveyed to and remain with the organization and are exclusive unless a checkmark is placed here ☐ and another Declaration on behalf of another entity is filed herewith.

I(we) acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I(we) hereby declare that all statements made herein of my(our) own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Name of Inventor	Signature	Date
Name of Inventor	Signature	Date
Name of Inventor	Signature	Date

KWALIS Qualitätsforschung Fulda GmbH — Name of Concern or Organization

Fuldaer Strasse 21, D-36160 Dipperz — Address

By Jürgen Strube — Name of Person Signing

Signature

Managing Director — Title

December 21, 2001 — Date

2234/50345

METHOD FOR PRODUCING A POTENTIATED PHARMACEUTICAL PRODUCT

[0001] The invention relates to a method for a producing potentiated pharmaceutical product for use in man, animals or plants.

[0002] Potentiated pharmaceutical products are used, for example, in homeopathic and anthroposophic medicine. The production method according to the Homöopathischen Arzneibuch (HAB) [Homeopathic Pharmacopoeia] comprises the processes of diluting and subsequently shaking (in the case of liquids) or of triturating (in the case of solids). These processes are referred to collectively (that is, diluting plus shaking or diluting plus triturating) as potentiating.

[0003] At the same time, a portion of the starting material, for example, 9 parts of the potentiating medium (the carrier substance) are shaken or triturated (potentiated). Usually, the diluting steps are 1 : 10 (D potency) and 1 : 100 and (C potency). Physicians, who use homeopathic pharmaceutical products, have confirmed that especially pharmaceutical products of the potency step D30 (corresponding to a dilution of $1 : 10^{30}$) and higher (for example, D200) are also effective. Moreover, the carrier substance mathematically no longer contains a molecule of the starting substance, since the order of magnitude of Avogadro's number (6.023×10^{23}) was exceeded at step D24 (or corresponding to C12). However, the effectiveness, which nevertheless occurs, was explained in the literature by stating that "information" is transferred from the starting substance to the carrier substance. The nature of this information or how it is stored is not known.

[0004] Scientifically, the treatment with potentiated drugs is controversial, since there are no generally accepted theoretical explanations for it. Furthermore,

no principle of action is known, which is compatible with known physiology and biochemistry. However, since the discovery of the potentiating principle more than 200 years ago, physicians and patients have time and again confirmed the therapeutic effectiveness of potentiated pharmaceutical products (also as veterinary medicines) and this form of pharmaceutical product and treatment has held up until now, in spite of the explanation predicament.

[0005] The preparation of appropriate pharmaceutical products is specified in the Homöopathischen Arzneibuch (HAB) [Homeopathic Pharmacopoeia]. As carrier substance (potentiating medium) for potentiated pharmaceutical products, water, alcohol (ethyl alcohol) and lactose are usually employed. Liquid pharmaceutical products are potentiated with alcohol or water, depending on the specification.

[0006] Until now, effectiveness studies with potentiated pharmaceutical products have not produced unambiguous results. Some studies have confirmed that the effectiveness, in comparison with a placebo, is increased. Other studies were unable to find an effect, which differed significantly from that of a placebo.

[0007] It can be concluded from this that manufacturers of such pharmaceutical products do not completely know the prerequisites for good effectiveness and attain these prerequisites only more or less by chance. It furthermore follows from this that the specifications of the HAB also do not completely include the prerequisites, which are necessary for attaining effectiveness.

[0008] The background for the, if anything, coincidental success is the fact that previously, it was not known how the carrier substance (the potentiating medium) takes over and stores the information of the starting substance and how the effectiveness of such types of potentiated pharmaceutical products comes about.

[0009] Natural water and tap water always contain traces of bound amino acids (proteinic materials) and free amino acids. When transferring the potentiating medium in air, additional small amounts of air-borne free and bound amino acids are taken up by the potentiating medium, as we have discovered in appropriate investigations.

[0010] Alcohol is produced by the fermentation of wine or fruit and the subsequent distillation to brandy or fruit liquor. The object of the distillation is to separate the aqueous portion from the alcoholic portion and to separate hazardous portions (such as a methyl alcohol) from the consumable alcohol. Aside from ethyl alcohol and (ethanol), further materials, such as other alcohols, aldehydes, esters and volatile proteins, amino acids, glycoproteins, lipoproteins, glycosides and lipids can additionally go over into the distillate. These additional materials are of decisive importance for the effectiveness of potentiated pharmaceutical products. This was previously not known. For this reason, varieties of alcohol are used, which contain these materials only in slight amounts, if at all.

[0011] The present production methods place great emphasis on the purity of the materials used for the production of pharmaceutical materials. A portion of the product quality is seen to lie therein. This may be a further reason for using alcohol qualities without the accompanying materials named above. However, the suitability for effective potentiated pharmaceutical materials is decreased further unwittingly as the degree of "purification" is increased.

[0012] Attention is paid to purity also in the case of water. For example, water is purified particularly by multiple distillations, complete desalination, ultrafiltration, reverse osmosis and irradiation with ultraviolet light (as individual methods or in combination) or, if sufficiently pure water is already available, the latter is checked at least for its purity. By producing the potentiated pharmaceutical products under clean room conditions, the proportion of air-borne bound and free amino acids in the air is also reduced. Correspondingly fewer such acids can go over into the potentiating medium.

REPLACEMENT PAGE

[0013] The effects of present methods of manufacturing potentiated pharmaceutical products and their raw materials in the direction of reducing their effectiveness as above are additive. However, this is hardly noticeable, since the measures are not all encountered simultaneously and suddenly and, instead, one measure after the other was introduced and introduced increasingly in the course of years and decades. Since it is so far not possible to check the effectiveness of potentiated pharmaceutical products, the abating effect is also unobserved in therapeutic practice. Admittedly, such decreases are suspected time and again by practitioners. However, it is hardly possible to check them.

[0014] It is an object of the invention to provide a method for the production of a potentiated pharmaceutical product, by means which the effectiveness of the potentiated product is increased significantly in comparison with that of the potentiated pharmaceutical products used at the present time.

[0015] Pursuant to the invention, this object is accomplished owing to the fact that a potentiating medium is used, which contains more than 400 nmoles/L of bound amino acid and/or 200 nmoles/L of free amino acids, that is, its content of amino acids is higher than that of potentiated media used at the present time.

[0016] This solution of the problem is based on an abandonment of the previous practice for the production of potentiated media. The scientific literature was searched for manufacturing conditions for homeopathic preparations, for which effectiveness studies (in groups of patients or in animal trials) provide the result of "no detectable effectiveness." In such cases, it was frequently noted that doubly-distilled water or particularly pure alcohol was used as the potentiating medium.

[0017] In addition to experience and an evaluation of the literature, there is a further justification for our measures to increase the effectiveness of potentiated pharmaceutical products. This justification is a new theoretical concept of how

potentiated pharmaceutical products store the information and how they could act. This theoretical concept follows on from known biochemical and physiological knowledge and finally also helps to understand the mode of action of potentiated pharmaceutical products.

[0018] Upon diluting and shaking or triturating (which can be regarded physically as a stimulating process), the electromagnetic structure of the molecules of the starting substance spreads out in their molecular environment. This acts on the proteinic substances and amino acids, contained in the potentiating medium, and converts these into an image of the starting substances. It is thus assumed that the amino acids and peptide molecules, which are particularly mobile in the aqueous medium, are rearranged under the influence of the molecules of the starting substance. Presumably they assume a structure, which simulates the structure of the starting substance (the pharmaceutical product, which is to be potentiated). Graphically, this can be envisioned to be similar to the production of a plaster impression (negative shape). In the next step, the plaster impression is filled up once again and a positive reproduction of the original is formed. In the next step, a negative impression is formed once again from this reproduction and on and so forth. A change in the action, corresponding to the positive and negative shapes, has actually been described in laboratory experiments in literature. However, to what this change may be attributed, was also not explained here.

[0019] The described passing on of structure can be regarded as the material basis of the transfer of information postulated in the literature.

[0020] The potentiating process can therefore consist therein that the disordered amounts of proteinic materials, contained in the potentiating medium, change their structure and, under the influence of the starting substance, which is present predominantly in an ordered manner, change over into a configuration similar to that of the starting substance. In the next potentiating step also, a similar process can be imagined once again. Around the ordered, proteinic

materials, a common field is formed, which is stronger than the proteinic substances of the potentiating medium, which admittedly are numerically more numerous, yet, because of their diversity, are not capable of a successful order. Upon shaking, the ordered minority imposes its order (structure, configuration) and impresses it on the other.

[0021] A similar change is known in biochemistry as the gene-antigen principle. Anti-antigens for the antigen are also known. This principle of the biochemical passing on of similitude can already also theoretically suggest that proteinic materials can participate in the potentiating process.

[0022] The passing on of structure may be possible, because proteinic materials are chain molecules or molecular complexes, which are present in water or alcohol as a movable structure. This structure is stabilized by hydrogen bonding. However, upon appropriate electromagnetic stimulation, such as that, which necessarily occurs during shaking in dipolar liquids, such as water and alcohol, these hydrogen bonds can be transformed. A similar process can be imagined in the case of proteinic substances and amino acids in lactose, only that the solid body cluster structures, which have become known in the last fifteen years, must be called upon here. Solid body clusters are structures between molecular structures and crystalline structures. They are ordered, but are not as immovable as solid molecules or crystals and, instead, are more prone to rearrange.

[0023] Polyamino acids are typical molecular complexes of the type under consideration here. They are known as peptides, proteins, enzymes, hormones, ovalbumins, albumins, etc. However, sugars are also suitable for forming complicated structures and are known as polysaccharides. This is all the more so if additional bonds to peptides are present (glycoproteins). Likewise, fatty and oily compounds (lipids) are capable of forming chains, again particularly in conjunction with peptides (lipoproteins).

[0024] Further possible molecular complexes of the type in question here are loose interlinkages of free amino acids. Amino acids are molecules with an acidic and a basic end. In proteins, there is a stable bond (covalent bond or peptide bond). Without peptide bonding, a loose attraction between basic and acidic ends of different amino acids is possible. This is a low-energy bond, similar to hydrogen bonding between different water molecules. Amino acids exist in great diversity; more than 300 types are known.

[0025] There can also be a weak attraction between sugar molecules, with the formation of microstructures. The cluster structures of solids are described in the literature. In the case often lactose, the participation of proteins and/or of amino acids is also regarded as decisive pursuant to the invention. However, they are represented differently, depending on the synthesis employed for the lactose.

[0026] The actual carrier of the information storage in potentiated pharmaceutical products, which has previously not been explained, is seen to lie in said structure-forming substances. The class of proteinic substances just happens to be the central substance group of biochemistry. Proteinic substances, such as enzymes, hormones, peptides, etc. participate in the majority of physiological reactions. This means that one may suspect that the potentiated pharmaceutical products also act in this manner. Owing to the fact that, as it were, a unilateral single substance (the starting substance) impresses its configuration in a plurality of other proteinic substances, one can imagine that this substance is more flexible in reaching all organs in man or animals, so that they can be more effective, without showing the one-sidedness of a particular chemical effect. This makes the effectiveness as well as the lack of side effects plausible.

[0027] The invention is based on the realization that the previously unknown active ingredient portions are located especially in the so-called "impurities" of water and alcohol and lactose. The invention therefore consists of using water, alcohols and lactose, which contain proteinogenic and physiological, free amino acids and/or proteinic material (bound amino acids) as a component of

potentiated pharmaceutical products or such materials are added to them for increasing the effectiveness.

[0028] The potentiated preparation, produced according to the inventive method, can also be used for being sprayed on lactose in tablet, spherical or other form or mixed or trituated therewith, in order to produce a potentiated pharmaceutical product with a different form of administration. It is particularly advantageous for the present invention if, as potentiating medium, an alcohol is used, which is obtained by fomenting plants, which, on the one hand, have a particularly high content of free and bound amino acids in the alcohol (such as blackthorn). Provisions can also be made when water is used as potentiating medium, so that the free and bound amino acids initially are taken from an alcohol and then added to the water.

Claims

1. A method for producing a potentiated pharmaceutical product for use in man, animals or plants, wherein a potentiating agent is used, the content of bound amino acids of which is more than 400 nmoles/L and/or of free amino acids the content of which is more than 200 nmoles/L, which are higher than that of the presently used potentiating media.

2. The method of claim 1, wherein a potentiating agent containing more than 800 nmoles/L of bound amino acids and/or more than 400 nmoles/L of free amino acids is used.

3. The method of claims 1 or 2, wherein a potentiating agent containing bound amino acids and/or free amino acids in amounts of about three times of the value of present potentiating media is used.

4. The method of at least one of the preceding claims, wherein the bound and/or free amino acids are added to the potentiating medium as accompanying materials.

5. The method of claim 4, wherein the accompanying materials are obtained from fruit.

6. The method of at least one of the preceding claims wherein the bound and/or amino acids are produced by adding natural, distilled fruit alcohol.

7. The method of at least one of the preceding claims, wherein a fruit alcohol with a high content of amino acids is used as the potentiating agent.

8. The method of claim 7, wherein an alcohol from blackthorn is used as a fruit alcohol.

9. The method of at least one of the preceding claims, wherein the free and/or bound amino acids are added by contact of the potentiating agent with natural air.

10. The method of at least one of the preceding claims, wherein water is used as the potentiating agent.

11. The method of at least one of the preceding claims, wherein lactose is used as the potentiating agent.

REPLACEMENT PAGE

UTILITY PATENT
OR DESIGN
SOLE OR JOINT

CROWELL & MORING, LLP
UNITED STATES LETTERS PATENT
DECLARATION AND POWER OF ATTORNEY

ATTORNEY'S DOCKET NO.
2234/50345

As a below named inventor, I declare that I believe I am the original, first and sole inventor if only one name is listed at Item 201 below, or a joint inventor if plural names are listed below at Items 201 et. seq. of subject matter which is claimed and for which a patent is sought for the invention entitled:

METHOD FOR PRODUCING A POTENTIATED PHARMACEUTICAL PRODUCT

which is described and claimed in:

101 [ ] the attached specification [X] the specification in application Serial No. 09/937,151 filed September 21, 2001
(for declaration not accompanying application papers)

and (*if applicable*) amended on

102 [ ] international (PCT) application No. filed and as amended on (if any)

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.
I acknowledge the duty to disclose all information known by me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.
I hereby claim the benefit of priority, under Title 35, United States Code, §119, of any foreign application(s) for patent or inventor's certificate listed in Item 103 below and have also identified in Item 103 below any foreign application(s) for patent or inventor's certificate having a filing date before that of the application for which priority is claimed.
I hereby claim the benefit, under Title 35, United States Code, §120, of any U.S. application(s) listed in Item 105 below. If this application is a continuation-in-part, insofar as the subject matter of any of the claims thereof is not disclosed in the prior U.S. application(s) identified in Item 105 below in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior U.S. application(s) identified in Item 105 below and the national or PCT international filing date of this application.

FOREIGN APPLICATION(S), IF ANY, FILED WITHIN 12 (6 if a Design) MONTHS PRIOR TO THE FILING DATE OF THIS APPLICATION THE PRIORITY OF WHICH WHERE PERMITTED IS HEREBY CLAIMED UNDER 35 U.S.C. §119

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED YES	PRIORITY CLAIMED NO
103 GERMANY	199 12 933.9	22/March/1999	X	
(PCT/DE00/00817)				

THIS APPLICATION IS A:	SERIAL NO.	FILED
[ ] CONTINUATION [ ] CONTINUATION-IN-PART [ ] DIVISION OF PRIOR U.S. APPLICATION		

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

(6)

JAMES F. MCKEOWN
Registration No. 25,406

HERBERT I. CANTOR
Registration No. 24,392

DONALD D. EVENSON
Registration No. 26,160

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SEND CORRESPONDENCE TO:	CROWELL & MORING, L.L.P. P.O. Box 14300 Washington, D.C. 20044-4300	DIRECT TELEPHONE CALLS TO: 202-628-8800

1-00 201	FULL NAME OF INVENTOR	LAST NAME Struhe	FIRST NAME Jürgen	MIDDLE NAME
	RESIDENCE CITIZENSHIP	CITY OR OTHER LOCATION D-36157 Ebersburg	STATE OR COUNTRY GERMANY	CITIZENSHIP GERMAN DEX
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Eichendorffstrasse 2, D-36157 Ebersburg, GERMANY		
2-00 202	FULL NAME OF INVENTOR	LAST NAME Stolz	FIRST NAME Peter	MIDDLE NAME
	RESIDENCE CITIZENSHIP	CITY OR OTHER LOCATION D-36157 Ebersburg	STATE OR COUNTRY GERMANY	CITIZENSHIP GERMAN DEX
	POST OFFICE ADDRESS	POST OFFICE ADDRESS Giebelrainer Weg 8, D-36157 Ebersburg, GERMANY		
3-00 203	FULL NAME OF INVENTOR	LAST NAME Maier	FIRST NAME Walter	MIDDLE NAME
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204	FULL NAME OF INVENTOR	LAST NAME Gutberlet	FIRST NAME Wolfgang	MIDDLE NAME
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205	FULL NAME OF INVENTOR	LAST NAME	FIRST NAME	MIDDLE NAME
	RESIDENCE CITIZENSHIP	CITY OR OTHER LOCATION	STATE OR COUNTRY	CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS		
206	FULL NAME OF INVENTOR	LAST NAME	FIRST NAME	MIDDLE NAME
	RESIDENCE CITIZENSHIP	CITY OR OTHER LOCATION	STATE OR COUNTRY	CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS		

☐ Seventh (and more) coinventors on page 3

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of any patent issue thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE December 21, 2001	DATE December 21, 2001	DATE December 21, 2001
SIGNATURE OF INVENTOR 204	SIGNATURE OF INVENTOR 205	SIGNATURE OF INVENTOR 206
DATE December 21, 2001	DATE	DATE